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(54) Title: A COMPOSITION FOR DISINFECTING OR WASHING MEDICAL INSTRUMENTS AND A PROCESS FOR THE PREPARATION THEREOF

(57) Abstract: A composition for disinfecting or cleaning a medical instrument and a preparation process thereof are provided. The composition includes 0.08 to 0.35% by weight of peracetic acid, 0.1 to 20% by weight of acetic acid, 1 to 6% by weight of hydrogen peroxide, 0.1 to 20% by weight of phosphoric acid, 0.1 to 5% by weight of 1, 1-diphosphonic acid, 0.001 to 10% by weight of at least one surfactant with alcoholic acid, 0.001 to 10% by weight of at least one surfactant with alcoholic groups at both terminals, 0.001 to 5% by weight of a corrosion inhibitor, and the remainder of the total composition being distilled water, reverse osmosis water or deionized water.



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**A COMPOSITION FOR DISINFECTING OR WASHING MEDICAL
INSTRUMENTS AND A PROCESS FOR THE PREPARATION
THEREOF**

5 Technical Field

 The present invention relates to a peracetic acid (PAA) composition for disinfecting or cleaning a medical instrument, the composition comprising a surfactant with alcoholic groups at both terminals, and a preparation process thereof.

10

Background Art

 Endoscopy has experienced widespread use for a variety of medical areas including digestive trouble diagnosis, and the number of cases of endoscopic examination is gradually increasing. In order to ensure safety and efficiency in endoscopic examination, it is important to prevent hospital infection that frequently arises during endoscopic surgery and to keep endoscopes functioning properly. Since around 15 1980, there has been an increasing awareness of the seriousness of hospital infection in America, England, Japan and other countries, and research into endoscope disinfection or cleaning is being extensively progressed.

 Hospital infection during endoscopy can affect any person in hospital, that is, not only patients but also doctors and even the hospital personnel may be affected by infection. Thus, it is necessary to take comprehensive measures for preventing hospital infection caused by 25 microorganisms, e.g., Helicobacter Pylori or Tuberculous Bacillus.

 In order to prevent hospital infection, it is also necessary to sufficiently clean not only endoscopes but also other medical instruments including a surgical operating instrument, general medical instrument, an anesthetic device, a pulmotor or peripheral devices thereof, an obstetric 30

and gynecological instrument, a dental device or a Chinese medical instrument.

Compositions for disinfecting or cleaning the medical instrument, that is, peracetic acid (PAA) compositions comprising peracetic acid, acetic acid and hydrogen peroxide, have been developed, as disclosed
5 in PCT publication Nos. WO 88/08667, WO 93/07909 and WO 94/14321, European patent application EP 596,493, U.S. Patent No. 6,168,808, etc.

The conventional PAA composition for disinfecting or cleaning a
10 medical instrument generally includes peracetic acid, acetic acid, hydrogen peroxide and, purified water, and further includes a stabilizer such as phosphoric acid or phosphonic acid, a nonionic surfactant such as sorbitan monopalmitate or polyoxyethylene cetyl ether, amine oxides, and the like. Since the disinfecting or cleaning composition exhibits
15 sterilizing effects fast, it is suitably used for automatic washers and manual cleaning.

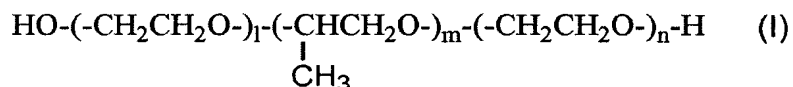
The disinfecting or cleaning composition with a low content of peracetic acid, for example, less than 1% by weight, presents limitations to its use because it exhibits poor cleaning ability to organic matter, e.g.,
20 mucus or other contaminants. Also, when the PAA composition is used in endoscopes, forceps or surgical operating instruments made of copper and zinc compounds and the like, corrosion may occur to those instruments.

In the case of using a PAA composition containing a conventional
25 surfactant, generation of foams cannot be effectively suppressed, so that the foams prevent the composition from contacting a medical instrument, resulting in poor disinfecting and cleaning efficiency.

Disclosure of the Invention

The present invention provides a peracetic acid (PAA) composition for disinfecting or cleaning a medical instrument, and its preparation process, the PAA composition comprising a surfactant with alcoholic groups at both terminals, which can minimize generation of
 5 foams and occurrence of corrosion.

According to one aspect of the present invention, there is provided a composition for disinfecting or cleaning a medical instrument, the composition comprising 0.08 to 0.35% by weight of peracetic acid, 0.1 to 20% by weight of acetic acid, 1 to 6% by weight of hydrogen peroxide,
 10 0.1 to 20% by weight of phosphoric acid, 0.1 to 5% by weight of 1,1-diphosphonic acid, 0.001 to 10% by weight of at least one surfactant represented by the formula (I), 0.001 to 5% by weight of a corrosion inhibitor, and the remainder of the total composition being distilled water, reverse osmosis water or deionized water:



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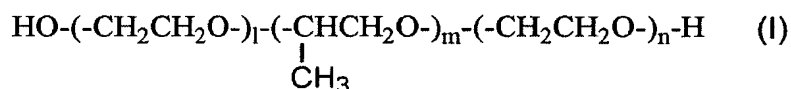
wherein l, m and n are integers between 1 and 50, and the sum of l and n is between 2 and 50.

According to another aspect of the present invention, there is provided a process for preparing a composition for disinfecting or
 20 cleaning a medical instrument, the process comprising (a) mixing 79 to 80% by weight of distilled water, reverse osmosis water or deionized water, 0.1 to 10% by weight of phosphoric acid and 0.1 to 1.0% by weight of 1,1-diphosphonic acid, (b) mixing 0.2 to 2.0% by weight of acetic acid with the solution obtained in step (a), (c) mixing 5 to 7% by
 25 weight of hydrogen peroxide with the solution obtained in step (b) to form peracetic acid, (d) warming the solution obtained in step (c) at 35 to 45°C for 4 to 7 hours and then maturing the same at room temperature, (e) mixing 0.001 to 5% by weight of at least one corrosion inhibitor selected

from the group consisting of sodium silicate, sodium nitrate, sodium benzoate, benzotriazole, polyacrylate copolymers with the solution obtained in step (d), and (f) mixing 0.001 to 10% by weight of at least one surfactant represented by the formula (I) with the solution obtained
 5 in step (e).

Best mode for carrying out the Invention

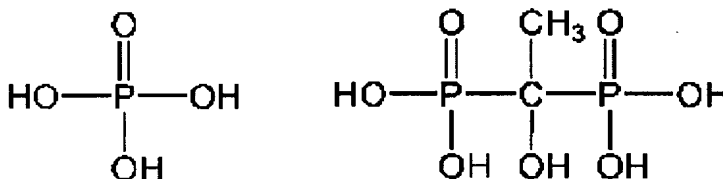
The composition for disinfecting or cleaning a medical instrument, includes 0.08 to 0.35% by weight of peracetic acid, 0.1 to 20% by weight
 10 of acetic acid, 1 to 6% by weight of hydrogen peroxide, 0.1 to 20% by weight of phosphoric acid, 0.1 to 5% by weight of 1,1-diphosphonic acid, 0.001 to 10% by weight of at least one surfactant represented by the formula (I), 0.001 to 5% by weight of a corrosion inhibitor, and the remainder of the total composition being distilled water, reverse osmosis
 15 water or deionized water:



wherein l, m and n are integers between 1 and 50, and the sum of l and n is between 2 and 50.

The peracetic acid and hydrogen peroxide are directly related to
 20 germicidal function and exist in an equilibrium state in the disinfecting or cleaning composition.

Phosphoric acid and 1,1-diphosphonic acid form a mixed stabilizer, each represented by the following formulas:

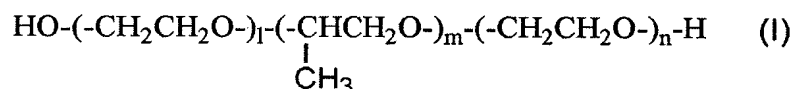


Phosphoric acid

1,1-diphosphonic acid

In the disinfecting or cleaning composition according to the present invention, the mixed stabilizer stabilizes peracetic acid and hydrogen peroxide. Phosphoric acid contained in the mixed stabilizer allows acidity for removing scales, thereby improving capability of removing scales, e.g., calcium carbonate (CaCO₃) or calcium sulfate (CaSO₄). In other words, the mixed stabilizer functions to stabilize the disinfecting or cleaning composition according to the present invention and to adjust the acidity thereof to be in a desirable range.

The disinfecting or cleaning composition according to the present invention includes a surfactant represented by the following formula:



wherein l, m and n are integers between 1 and 50 and the sum of l and n, i.e., l+n, is in a range from 2 to 50.

In the surfactant, the sum of l and n, corresponding to the amount of an ethylene oxide moiety, is preferably from about 4 to about 50 mole, and m corresponding to the amount of a propylene oxide moiety is preferably from about 5 to about 40 mole. Also, an average molecular weight of the surfactant is preferably from about 1500 to about 3000, more preferably about 2,500. Examples of the surfactant useful in the present invention include any surfactants which are commercially available in an amount within the range defined above, including polyoxyethylene and oxypropylene block copolymers and the like, e.g., Koremul-PE62 (Hannong Chemicals Inc., Korea).

Since the surfactant has high stability and cleaning efficiency, and low foamability and toxicity with respect to peroxides, cleaning performance of the disinfecting or cleaning composition according to the

present invention can be enhanced using only a small amount of peracetic acid. Also, since the surfactant exhibits a low surface tension and low foaming, it can minimize environmental problems due to the presence of an antifoamer used in conventional medical instrument
5 cleaning.

Examples of the corrosion inhibitor useful in the present invention include at least one selected from the group consisting of sodium silicate, sodium nitrate, sodium benzoate, benzotriazole and polyacrylate copolymers, which are preferably used because they have corrosion
10 inhibiting properties against aluminum, copper and/or zinc compounds. Preferably, the polyacrylate copolymer has a molecular weight from about 50,000 to about 100,000 and a pH from about 2 to about 3, and examples thereof include copolymers commercially available in the trade-
names of Acrysol from Rohm and Hass Co., Sokalan from BASF Corp.,
15 TPA50 from Taechang Corp., and so on.

The composition for disinfecting or cleaning a medical instrument according to the present invention employs water as the solvent, distilled water, that is, substantially pure water that is not contaminated, is preferred, and reverse osmosis (RO) water or deionized (DI) water is
20 more preferred.

The amounts of all ingredients contained in the disinfecting or cleaning composition are amounts of the respective ingredients contained in the finally obtained composition at an equilibrium state. Preferably, the disinfecting or cleaning composition being at an
25 equilibrium state comprises 0.08 to 0.35% by weight of peracetic acid, 0.1 to 20% by weight of acetic acid, and 1 to 6% by weight of hydrogen peroxide. Of course, the amounts may slightly deviate from the range defined above in view of sufficient disinfecting or cleaning efficiency, which should, however, be construed to be within the range defined

above for the disinfecting or cleaning composition according to the present invention.

Also, phosphoric acid and 1,1-diphosphonic acid as a stabilizer and a scale remover, are preferably used in amounts of 0.1 to 20% and 0.1 to 5%, by weight, respectively. The amounts of phosphoric acid and 1,1-diphosphonic acid may also slightly deviate from the range defined above in view of sufficient stabilizing and descaling efficiency, which should, however, be construed to be within the range defined above for the disinfecting or cleaning composition according to the present invention.

The surfactant represented by the formula (I) is preferably used in an amount of 0.001 to 10% by weight, more preferably 0.5 to 5% by weight.

The corrosion inhibitor is preferably used in an amount of 0.001 to 5% by weight. The amount of the corrosion inhibitor may also slightly deviate from the range defined above in view of sufficient anticorrosion efficiency, which should, however, be construed to be within the range defined above for the disinfecting or cleaning composition according to the present invention.

Distilled water, RO water or DI water supplied as the solvent or diluent in the disinfecting or cleaning composition according to the present invention is used in an appropriate amount to be the remainder to 100%, forming the final composition with other ingredients.

Medical instruments that can be applied to the disinfecting or cleaning composition according to the present invention include, but not limited to, an endoscope, a surgical operating instrument, general medical instrument, an anesthetic device, a pulmotor or peripheral devices thereof, an obstetric and gynecological instrument, a dental device, a Chinese medical instrument and the like.

In accordance with another aspect of the present invention, there is provided a process for preparing the composition for disinfecting or cleaning a medical instrument, the process comprising (a) mixing 79 to 80% by weight of distilled water, reverse osmosis water or deionized water, 0.1 to 10% by weight of phosphoric acid with 0.1 to 1.0% by weight of 1,1-diphosphonic acid, (b) mixing 0.2 to 2.0% by weight of acetic acid with the solution obtained in step (a), (c) mixing 5 to 7% by weight of hydrogen peroxide with the solution obtained in step (b) to form peracetic acid, (d) warming the solution obtained in step (c) at 35 to 45°C for 4 to 7 hours and then maturing the same at room temperature, (e) mixing 0.001 to 5% by weight of at least one corrosion inhibitor selected from the group consisting of sodium silicate, sodium nitrate, sodium benzoate, benzotriazole, polyacrylate copolymers with the solution obtained in step (d), and (f) mixing 0.001 to 10% by weight of at least one surfactant represented by the formula (I) with the solution obtained in step (e).

The warming is performed for the purpose of facilitating a reaction between hydrogen peroxide and acetic acid. In the maturing of the solution, the amount of hydrogen peroxide is adjusted to an appropriate level, for example, to less than 6% by weight. The maturing is preferably performed for about 3 days.

According to the present invention, a contact time of about 5 to about 10 minutes can be used to effectively disinfect or clean a medical instrument, such as an endoscope, a surgical operating instrument, a general medical instrument, an anesthetic device, a pulmotor or peripheral devices thereof, an obstetric and gynecological instrument, a dental device or a Chinese medical instrument. The contact time is adjustably increased or decreased as needed. In the disinfecting or cleaning composition according to the present invention, since peracetic acid is contained at a low concentration level, it is not necessary to

separately dilute the composition. However, the disinfecting or cleaning composition according to the present invention can be appropriately diluted, by necessity, within the range acceptable in the art. An aqueous solvent, preferably distilled water, RO water or and DI water,
5 can be used as a diluent.

The present invention will now be described in more detail referring to Examples, and the present invention is not limited thereto by any means.

Example 1

10 88.3 g of RO water, 1.0 g of phosphoric acid and 0.1 g of 1,1-diphosphonic acid were mixed together and then mixed with 1 g of acetic acid, followed by mixing with 6 g of hydrogen peroxide, thereby preparing peracetic acid and warming the same at 35 to 45°C for about 7 hours. The resultant material was agitated at room temperature to be
15 matured, and 0.5 g of TPA50 commercially available from Taechang Corp. Korea, was added thereto, followed by sequentially adding 0.2 g of sodium benzoate, 0.2 g of benzotriazole, 0.5 g of sodium nitrate, 0.1 g of sodium silicate, and, finally, 2 g of a polyoxyethylene and oxypropylene block copolymer commercially available from Hannong Chemicals Inc., in
20 the trade name of Koremul – PE62, thereby preparing the disinfecting or cleaning composition according to the present invention. Concentration of peracetic acid and hydrogen peroxide contained in the prepared composition were 0.35% and 2.02%, respectively.

25 Example 2

The composition for disinfecting or cleaning a medical instrument was prepared in the same manner as in Example 1, except for 0.3 g of acetic acid being used. Concentrations of peracetic acid and hydrogen peroxide contained in the acquired composition were 0.20% and 2.10%,
30 respectively.

Example 3

The composition for disinfecting or cleaning a medical instrument was prepared in the same manner as in Example 1, except for 0.1 g of acetic acid being used. Concentrations of peracetic acid and hydrogen peroxide contained in the acquired composition were 0.09% and 2.20%, respectively.

Example 4

The composition for disinfecting or cleaning a medical instrument was prepared in the same manner as in Example 1, except for 0.3 g of acetic acid and 3.0 g of hydrogen peroxide being used. Concentrations of peracetic acid and hydrogen peroxide contained in the acquired composition were 0.18% and 1.01%, respectively.

Example 5

The composition for disinfecting or cleaning a medical instrument was prepared in the same manner as in Example 1, except for 0.1 g of acetic acid and 3.0 g of hydrogen peroxide being used. Concentrations of peracetic acid and hydrogen peroxide contained in the acquired composition were 0.08% and 1.05%, respectively.

Example 6: Corrosion test (1)

Corrosion products and impurities were removed from a test sample surface made of aluminum using 70% nitric acid and was brought into contact with the composition prepared in Example 1 for about 5 hours, followed by weighing the test sample. Then, a corrosion rate was calculated using the following equation:

$$\text{Corrosion rate} = 534 \times (\text{Loss in weight}) / (D \times A \times T)$$

wherein D represents the density indicated in unit of g/cm^3 , A represents the area of the test sample indicated in unit of in^2 and T represents the time indicated in unit of hours. The corrosion rate of the composition obtained by the above equation was 1.67 mm/yr. When compared with
5 the corrosion rate of the conventional PPA composition, that is, about 2.68 mm/yr, the disinfecting or cleaning composition according to the present invention showed a significant reduction in the corrosion rate.

Example 7: Corrosion test (2)

10 Corrosion products and impurities were removed from a test sample surface made of brass using 20% hydrochloric acid and was brought into contact with the composition prepared in Example 1 for about 30 minutes, followed by weighing the test sample. Then, the corrosion rate obtained in the same manner as in Example 6 was 5.25
15 mm/yr. When compared with the corrosion rates of the conventional PPA compositions, that is, about 109.37 mm/yr, the disinfecting or cleaning composition according to the present invention showed a significant reduction in the corrosion rate.

20 Example 8: Cleaning/disinfecting test

This evaluation was carried out using the composition prepared in Example 1. An endoscope which is commercially available from Olympus Corp. in Model No. GIF-P20 was used for about one month. Disinfecting and cleaning tests were performed based on the diagnostic
25 guidelines provided by the Korean Society of Gastrointestinal Endoscopy. After cleaning the endoscopes, specimens were harvested from two parts of each endoscope for culturing.

30 ml of a saline solution was slowly injected into a suction channel through a biopsy cavity using a 50 ml needle and the water
30 falling down to a distal end of an insertion site of the endoscope was

collected in a sterile tube, yielding a specimen S-1. Also, a portion between the distal end of the insertion site of the endoscope and a body part of the endoscope was smeared with a cotton swab wet by a saline solution, yielding a specimen S-2. To examine contamination of an automatic endoscope washer, the automatic endoscope washer was rinsed with a rinse solution and 100 ml of the rinse solution was sampled twice.

The specimen S-1 and a specimen from the rinse solution of the automatic endoscope washer were allowed to pass through each 0.22 μ m nitrocellulose membrane filter under negative pressure. Immediately thereafter, the membrane filters were evenly spread plated onto blood agar plates. The specimen S-2 sampled with a cotton swab was evenly inoculated directly on a blood agar broth. The disinfection test result is as follows.

Table 1

Specimen S-1		Specimen S-2	
Before treatment	After treatment	Before treatment	After treatment
2.7×10^3	-	5.3×10^3	-

As ascertained from Table 1, the composition according to the present invention can effectively disinfect and clean endoscopes effectively without generating foams, and no corrosion occurs to the endoscopes.

Example 9: In vitro disinfection test

A description of the disinfection test procedure for bacteria and fungi follows.

1. Bactericidal test

0.1 ml of a bacteria solution, which was cultured in a nutrient broth and a tryptic soy broth for 24 hours, and 10 ml of the composition

prepared in Example 1, were shakingly mixed and reacted for one minute. Then, 1 ml of the reactant solution was put in a test tube having 9 ml of a neutralizer containing 4.26 % sodium phosphate dibasic, 3% tween, 0.5 % sodium thiosulfate pentahydrate, 0.3 % L- α -lecithin and 0.1 % L- histidine. 1 ml of the mixed solution was diluted 10 times with peptone-containing water. 0.1 ml each of the concentrated mixed solution and a 10-fold diluted solution thereof were spread plated onto at least two previously coagulated agar plates. Following incubation at 30 to 35°C for 3 days, colonies per plate were counted and then the average colony number per plate was calculated.

2. Fungicidal test

0.1 ml of a fungi solution, which was cultured in a yeast malt broth for 48 hours, and 10 ml of the composition prepared in Example 1, were shakingly mixed and reacted for 10 minutes. After 10 minutes, 1 ml of the reactant solution was put in a test tube having 9 ml of a neutralizer containing 4.26 % sodium phosphate dibasic, 3% tween, 0.5 % sodium thiosulfate pentahydrate, 0.3 % L- α -lecithin and 0.1 % L- histidine. 1 ml of the mixed solution was diluted 10 times with peptone-containing water. 0.1 ml each of the concentrated mixed solution and a 10-fold diluted solution thereof were spread plated onto at least two previously coagulated agar plates. Following incubation at 20 to 25°C for 7 days, colonies per plate were counted and then the average colony number per plate was calculated.

The disinfection test results of the bacteria and fungi are as follows.

Table 2

Strain	Initial strain number	Contact time (min.)	Final strain number
Staphylococcus aureus ATCC 653	2.6×10^7	1	-

Candida albicans ATCC 10251	1.7×10^6	10	-
MRSA	3.4×10^6	1	-
Escherichia coli ATCC 2592	5.6×10^7	1	-
Pseudomonas aeruginosa ATCC 9027	2.6×10^6	1	-
Klebsiella pneumoniae ATCC 10051	1.9×10^7	1	

As ascertained from Table 2, the disinfecting or cleaning composition of the present invention can effectively kill bacteria and fungi.

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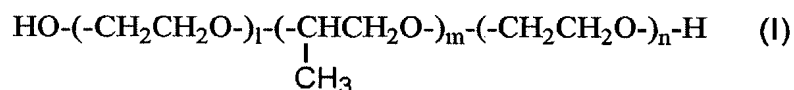
Industrial Applicability

As described above, the disinfecting or cleaning composition according to the present invention can effectively enhance cleaning efficiency without causing a reduction in sterilizing efficiency. Also, problems due to foams and corrosion can be minimized.

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What is claimed is:

1. A composition for disinfecting or cleaning a medical instrument, the composition comprising 0.08 to 0.35% by weight of peracetic acid, 0.1 to 20% by weight of acetic acid, 1 to 6% by weight of hydrogen peroxide, 0.1 to 20% by weight of phosphoric acid, 0.1 to 5% by weight of 1,1-diphosphonic acid, 0.001 to 10% by weight of at least one surfactant represented by the formula (I), 0.001 to 5% by weight of a corrosion inhibitor, and the remainder of the total composition being distilled water, reverse osmosis water or deionized water:



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wherein l, m and n are integers between 1 and 50, and the sum of l and n is between 2 and 50.

2. The composition of claim 1, wherein an average molecular weight of the surfactant is from about 1500 to about 3000.

3. The composition of claim 1, wherein an average molecular weight of the surfactant is about 2,500.

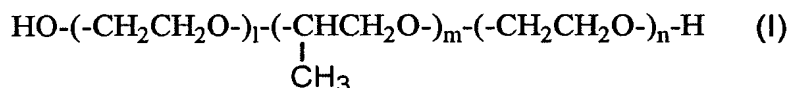
4. The composition of claim 1, wherein the medical instrument is an endoscope, a surgical operating instrument, general medical instrument, an anesthetic device, a pulmotor or peripheral devices thereof, an obstetric and gynecological instrument, a dental device, or a Chinese medical instrument.

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5. The composition of any one of claims 1 through 4, wherein the corrosion inhibitor is at least one selected from the group consisting

of sodium silicate, sodium nitrate, sodium benzoate, benzotriazole and polyacrylate copolymers.

6. A process for preparing a composition for disinfecting or
 5 cleaning a medical instrument, the process comprising:
- (a) mixing 79 to 80% by weight of distilled water, reverse osmosis water or deionized water, 0.1 to 10% by weight of phosphoric acid and 0.1 to 1.0% by weight of 1,1-diphosphonic acid;
 - (b) mixing 0.2 to 2.0% by weight of acetic acid with the solution
 10 obtained in step (a);
 - (c) mixing 5 to 7% by weight of hydrogen peroxide with the solution obtained in step (b) to form peracetic acid;
 - (d) warming the solution obtained in step (c) at 35 to 45°C for 4 to 7 hours and then maturing the same at room temperature;
 - 15 (e) mixing 0.001 to 5% by weight of at least one corrosion inhibitor selected from the group consisting of sodium silicate, sodium nitrate, sodium benzoate, benzotriazole, polyacrylate copolymers with the solution obtained in step (d); and
 - (f) mixing 0.001 to 10% by weight of at least one surfactant
 20 represented by the formula (I) with the solution obtained in step (e):



wherein l, m and n are integers between 1 and 50, and the sum of l and n is between 2 and 50.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/KR03/01742

A. CLASSIFICATION OF SUBJECT MATTER**IPC7 C11D 3/36**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7 C11D, A01N, A61K, A61L, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 Korean Patents and applicants for inventions since 1975. Korean Utility Models and applicants for inventions since 1975.
 Japan Utility Models and applicants for inventions since 1975.

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 NPS, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5508046 A (Minntech corp.) 16.Apr.1996 See the Column1, line54 - column 2, line 53.	1 - 6
A	JP 12-51350 A (Nissho corp.) 22.Feb.2000 See the Claim 1,2	1 - 6
A	JP 02-193905 A (L'Air Liquide) 31.Jul.1990 See the Claim 1-3, whole document	1 - 6
A	WO 93/07909 A (Solvay Interlox Limited) 29.April.1993 See the whole document	1 - 6

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

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Date of mailing of the international search report

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Name and mailing address of the ISA/KR



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INTERNATIONAL SEARCH REPORT

Information on patent family members

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